Remarks and Response

To more clearly define the method of the invention in the broadest terms, claim 250 is now amended. To clarify the term "new" (defined in the specification at paragraph [0007] as "previously unrecognized") as meaning novel, as it has been described throughout Applicant's arguments of record, the term "novel" is added by amendment. Support may be found for the term in, for example, paragraph [0003], wherein novel adverse event information is described as valuable because of it's patentability (*i.e.*, proprietary). Further amendments to claims 250-294 are fully supported by the now-cancelled claims, in further light of the steps provided in Applicant's flow-charts in the figures, and in the remainder of the specification. Amendments made in response to the Examiner's comments in the Office Action are addressed below and support will be discussed at that point.

New claims 295-300 are added. Support may be found for claims 295 and 296, at least at paragraphs [0044] and [0049] of the specification; for claim 297 at least at paragraph [0097]; for claim 298 at least at paragraph [0036]; and for claims 299 and 300 at least at paragraph [0074]. No new matter has been added.

Response to the Rejection under 35 U.S.C. §112, first paragraph

The Examiner has rejected Applicant's pending claims under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. In making this rejection the Examiner states that Applicant fails to "describe how the new adverse event is derived from the adverse event data sources. However, the rejection is traversed for the following reasons.

Applicant's instant invention is related to, and an improvement over, US Pat. Nos. 6,219,674 and 6, 584,472 (US Ser. No. 09/804,289), both of which are expressly incorporated by reference in the specification (paragraph 0003). Improved methods are patentable subject mater. Thus, the incorporated patents, by their reference, provide one skilled in the art with additional information, which has previously been published and need not be reiterated in the pending Application.

However, contrary to the limitations found in the prior art, the pending application provides an improved method, in at least claim 250, by identifying new "essential"

adverse event information, as opposed to the prior art methods, which searched for any new adverse event. As defined in the specification, one is taught in at least paragraphs [0004], [0086] and [0087], how to identify "essential" information. Moreover, one skilled in the art of the present invention would also be familiar with the definition of essential adverse event information, as set forth in 21 C.F.R. 201.57. See Exhibit P attached hereto.

It has been consistently held that the first paragraph of 35 U.S.C. 112 requires nothing more than objective enablement. *In re Marzocchi*, 169 USPQ 367 (CCPA 1971). In satisfying the enablement requirement, an application need not teach, and preferably omits, that which is well known in the art. *Hybritech, Inc. v. Monoclonal Antibodies*, Inc., 231 USPQ 81 (Fed. Cir. 1986);

As Applicant has stated in the specification, "the government has carefully established codes and rules under which, for example in the medical field, manufacturers and/or distributors are required to notify or warn the public of known adverse events which could occur when certain products, including drugs, medicaments and the like, are ingested or used by human or veterinary patients." See specification paragraph [0004]. The final determination of what is "essential" information is determined by a regulatory agency such as the FDA. See paragraph [0086].

Thus, one skilled in this art would readily turn to the FDA to learn what is meant by "essential information." Moreover, as stated at paragraph [0087], "New adverse event information that is "essential" is of great commercial value since if this information is proprietary, for example patented in the form a new use, it can be used to exclude potential competitors from selling a product which would require the essential information. In order for a company searching through raw adverse new uses, to maximize profits from such a search, the "essential" new uses should ideally be separated from other new uses. By limiting the protection for such new data, *e.g.*, patenting, and limiting petitions to regulatory agencies to only the "essential" new uses, a company saves time and money by avoiding expending time on adverse event information that has little commercial value."

Accordingly, since the definition is known to one of ordinary skill in the art familiar with all relevant publications, including 21 C.F.R. 201.57, Applicant respectfully requests that the rejection be withdrawn.

Response to the Rejection under 35 U.S.C. §112, second paragraph

The Examiner has rejected Applicant's pending claims under 35 U.S.C. §112, second paragraph as failing to point out and distinctly claim that which Applicant regards to be the invention. In making this rejection the Examiner states that in claim 250, Applicant's preamble refers to a "new use for" a product, while "Applicant claims a database of 'essential adverse event information.'" Moreover, for the purpose of the rejection the Examiner states he has assumed that "**no**" difference (emphasis by Examiner) exists between or among the claim elements defined as:

- One data source comprises adverse event data;
- One previously known adverse event;
- Identifying at least one new essential adverse event; and
- Proprietary adverse event information.

However, the rejection is traversed for the following reasons.

Applicant appreciates the Examiner's comments and has amended claim 250 accordingly. The term "new characteristic" has been removed to avoid confusion with the intended claim to the novel method of use for the product, wherein the new use is derived by using a novel process. This is analogous to a product-by-process type claim, but instead the claims cover a "new use" derived from a process. The process is novel and patentable, and patents have been granted to Applicant on the process.

With regard to the Examiners conclusion that there is no difference between the following elements of claim 250: "one data source comprises adverse event data;" "one previously known adverse event;" "identifying at least one new essential adverse event," and "proprietary adverse event information," such a conclusion is impossible. The Examiner cannot possible assume that a step, such as "identifying" is in no way different from a data source, or and event or information, or that any of those three elements are identical and interchangeable. In fact, the subject passage simply describes a novel process of comparing adverse events to adverse events that are already known to find

"new" (novel) adverse events. One identifies (the "establishing" step) that an adverse event is novel and essential. Applicant is the first to teach this process, and it is a novel process. Accordingly, Applicant's method meets the requirements under 35 U.S.C. §112, second paragraph.

The "distinctly claiming" requirement of 112 is met by Applicant's claims, in that the claims have *clear and definite meaning when construed in the light of the complete patent document*. While the claim language under consideration may be broad, breadth is not indefiniteness. Instead, the second paragraph of section 112 simply requires the claims to set forth and circumscribe a particular area with a reasonable degree of precision and particularity. *Buell v. Beckestrom*, 22 USPQ2d 1128, 1133 (BPAI 1992).

To reiterate Applicant's arguments of record: "The public is entitled to know the scope of the claims, but must look to both the patent specification and the prosecution history, especially where there is doubt concerning the scope of the claims." *Texas Instruments v. ITC*, 10 USPQ2d 1257, 1264 (Fed. Cir. 1989). "[I]f the claims, read in the light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." Quoting *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 225 USPQ 634, 641 (Fed. Cir. 1985). *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986). Consequently, so long as the method is clear, it is not requisite under patent law that absolutely every step of the claimed method be delineated in the claim, if one of ordinary skill can determine the additional information from the specification or prosecution history. Accordingly, since Applicant's claims are distinct and the information supporting the claims is provided by the specification, that is, in the patent document as a whole, the rejection under 35 U.S.C. 112, second paragraph, is moot. Applicant, therefore, respectfully asks that the rejection be withdrawn.

Response to the Rejection under 35 U.S.C. §101

The Examiner has rejected Applicant's pending claims under 35 U.S.C. §101, as directed to non-statutory subject matter. In making this rejection the Examiner has interpreted Applicant's invention as directed to the natural exception of a "natural phenomenon," and as such is not patentable. The Examiner states that:

> Furthermore, the present invention does not have real world value, i.e., it is not useful, concrete and tangible. The present invention claims "A new use for a product" for a product that is well-known and expected in the art. MPEP § 2105 states "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252,1254,195 USPQ 430,433 (CCPA 1977).

Further the Examiner cites 35 U.S.C. §101 which reads as follows: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

However, Applicant responds that claim 250 has been amended to refer to a "novel responsive use" rather than a "new characteristic." The "novel use" pertains to a method of avoiding or decreasing the risk of an adverse event.

The statute allows for patenting "any new and useful improvement" of a process. Safer uses of a composition are patentable, just as new efficacious uses of a product are patentable. Applicant's pending claims pertain to safer methods of using a product by informing a user of the risks and/or how to avoid the risks. The scope of claim 250 is clearly limited by the identifying step, which operates "responsive to identifying of the essential novel adverse event." This implies that on learning of an essential novel adverse event, one establishes a novel use, which is "responsive," meaning - giving a response, quick to respond.

The claims are supported by paragraph [0077] ("In a preferred application, the systems described herein are used to develop new proprietary safer uses for drugs that are already generic or soon to become generic." Further support is found in paragraph [0072] ("Users might seek patent protection for new therapeutic uses for existing products or devices based on newly discovered essential adverse event information. Similarly, users might seek protection for new labeling necessitated by the discovery of the new essential adverse event information. For any new use discovered by the systems according to the present invention, the instructions accompanying the product or device for which the new use is identified should desirably warn newly-identified high risk users

of the product or device to avoid using the product or device.") and by paragraph [0070] ("It is not the intent of this invention to encompass an "expanded use" relating to an unexpected phenomenon associated with a product or device. "Expanded use" is used herein to mean other uses for a product or device in addition to currently known uses for the product or device. For example, if an unexpected phenomenon associated with blood pressure medicine is hair growth, then the use of blood pressure medicine may be expanded to include use as a hair tonic. By comparison, expanded uses for a medical product or device are not created by discovery of adverse events, rather such uses are determined by performing extensive clinical trials and obtaining regulatory approval for marketing the new use of the product or device. On the other hand, the invention is intended to encompass a restricted use, *i.e.*, avoiding, when possible, use of the product or device by methods involving same, or by using same, that are at increased risk for an adverse event. A new useful characteristic of a product or device responsive to identifying an essential adverse event, e.g., providing a written warning with the product to a consumer, is also encompassed by the invention. New restricted uses are primarily derived by discovering an adverse event because manufacturers are required to disclose possible adverse events associated with use of a product or device, even if the adverse event has not been proven to occur in a specific risk group or situation. However, the invention is intended to encompass a use that allows a group, previously considered to be at high risk, to use a product by better defining the high risk group, although, this is neither an expanded nor a restricted use.").

The claims do not, nor are they intended to, claim a composition. Rather, they claim a new therapeutic use or safer uses, which can include informing users of an adverse event. Such a result is useful, concrete and tangible because it helps avoid adverse events. Conversely, if adverse events occur, Applicant's invention alerts users to the causes of the adverse event, so that the circumstances causing the adverse event can be reversed, or at least the use of the product can be discontinued before the adverse event gets worse. While warning may be inherent, it is not inherent to warn others about an adverse event *that one does not know about.*

Hence, the rejection under 35 U.S.C. §101 is not appropriate. In fact, Applicant's method meets the requirements of 35 U.S.C. §101, and the present rejection is moot in

light of Applicant's amendments. Applicant, therefore, respectfully asks that the rejection be withdrawn.

Response to the Rejection under 35 U.S.C. §103(a)

The Examiner has rejected Applicant's claims 250, 256 and 257 under 35 U.S.C. §103(a), as obvious and unpatentable over Leet (US Pat. No. 6,000,828), in further view of Rivette (US Pat. No. 5, 991,751). In making this rejection the Examiner has cited several passages from Leet, which the Examiner infers teaches many of the elements of Applicant's claims. However, upon review, the cited passages from Leet do not teach the express elements of Applicant's claims 250, 256 or 257.

The examiner cites Leet, the full relevant sections are as follows:

A. Accessing one or more data sources [Leet Figure 2];

B. Where at least one data source comprises adverse event data [Figure 2, drug interaction database 28e; Leet column 26, lines 5-61];

C. Analyzing and comparing adverse event data associated with a product of manufacture or device, where at least one previously known adverse event associated with the product or device [detect any drug interaction: Leet column 18, lines 60-65];

D. Identifying at least one new essential adverse event associated with the product or device from the adverse event data, and then responsive to identification, identifying the at least one new characteristic of, or use for, the product or device [pharmacist performs reviews: Leet column 18, lines 55-60].

Applicant responds that "identifying of at least one new essential adverse event" is a critical steps in Applicant's claimed invention, whereas the passage cited by the examiner (col. 18, lines 55-60] simply does not relate to the claimed step. According to Applicant's written description, one must "identify" (establish) that an adverse event is "novel." Conversely, the passage cited by the examiner does not mention adverse events. Moreover, the cited passage fails to teach, or even consider, establishing that an adverse event is "novel." Third, the cited passage does not tell how the pharmacist is going to find a "novel" adverse event. In the cited passage, the pharmacist is not privy to "novel" information, nor does he perform tasks that would lead to discovery of the "novel" adverse events. A pharmacist would have access to known adverse events, but he would not necessarily have access to a source of potential novel adverse events. If an adverse

event is reported to a pharmacist, as occurs in some occasions, the adverse event is not "novel" within the definition of Applicant's invention, because some one else has already made the discovery – which is why it is *reported* to the pharmacist. Consequently, if the discovery is not made by the pharmacist without third-party intervention – it is not novel to him for patenting purposes.

E. Documenting inventorship of the at least one new characteristic of, or use for, the product or device [message sent to physicians: Leet column 19, lines 5-10].

Applicant responds that the passage cited by the Examiner does not relate to the cited limitation in Applicant's pending claim (which no longer refers to a "characteristic"). Leet states nothing about "documenting inventorship," nor does it even mention or consider "inventing," in general. In Leet, the pharmacist reviews the pharmaceutical order to determine if it was a recommended therapy (dose). The assessment by the pharmacist as to whether a requested order is a recommended dose, does not equate to whether a treatment is novel. There are many treatments that are widely used that are not recommended. Just because a pharmacist determines that a requested treatment is not the recommended treatment, does not mean the treatment is novel or that the requesting physician is an inventor of such method,

F. Creating a proprietary essential adverse event information database which stores the one new characteristic or use [drug interaction database 28e: Leet column 26, lines 5-6]. Note the claim has been modified to "at least one novel adverse event."

Applicant responds that the cited passage from Leet is unrelated to the claim limitation of claim 250. The Leet passage (Leet column 26, line 5) states "it can monitor adverse drug reactions to drugs as treatment progresses, and use that information to modify the DRG protocol treatments." The passage of Leet refers to the fact that if a patient has an adverse event from a drug, the medical provider can bill more for treatment of the patient than can be billed if the patient has no adverse event. The term "DRG" in the passage refers to "Diagnosis Related Groups." Leet does not discuss "proprietary" (patentable) adverse event information. By contrast, the claim limitation of claim 250 pertains to creating a database of the "proprietary" (patentable) new adverse event information.

G. Wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication. [Rivett abstract] From the Rivette abstract, the Examiner states that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leet to include wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication as taught by Rivette for the purpose of managing an inventor's database of intellectual property."

Applicant responds that he agrees with the Examiner that Leet does not teach all of the claim elements or limitations of Applicant's invention. To fill that deficiency, the Examiner has relied upon the Rivett abstract, but in Rivett there is no mention of creating a "database of proprietary essential adverse event data." While Rivett does mention a patent database, the claim limitation mentions a specific type of patent database. Thus, neither Leet nor Rivett, alone or combined, suggest a database of "proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. Consequently, in accordance with patent law, if the cited prior are fail to teach each and every element of Applicant's invention, there can be no finding of obviousness of claim 250.

2. Regarding the Examiner's Rejection of claim 257.

The claim has been amended to correct its dependency. Nevertheless, the Examiner has rejected claim 257 based on a general obviousness rejection without providing specific reference. Applicant respectfully points out that claim 257 does not require "commercialization" – rather there is a limitation that there be "commercial data." The claim pertains to a database containing "raw commercial data," but the Examiner's rejection has nothing to do with a database on "raw commercial data." Conversely, claim 257 mentions neither "commercialization" nor sales documents that are mentioned in the Examiner's statement to support the rejection. In fact, the object (utility) of claim 257 is to use sales data to help detect specific candidates to screen.

Accordingly, the obviousness rejections are improper, and Applicant respectfully asks that they be withdrawn in light of Applicant's comments.

Response to the Rejection under 35 U.S.C. §103(a)

The Examiner has rejected Applicant's claims 251, 252, 254 and 258 under 35 U.S.C. §103(a), as obvious and unpatentable over Leet (US Pat. No. 6,000,828) and Rivette (US Pat. No. 5, 991,751), in further view of Colombo (US Pat. No. 5,678,234). In making this rejection, the Examiner has stated that "determining value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event" [Colombo col. 3, lines 60-65].

Applicant responds that he agrees with the Examiner admits that Leet and Rivette do not disclose the elements of claim 251,252, and 254. In an attempt to fill that gap, the Examiner relies on Colombo for a program of sulfur removal and ways to utilize the sulfur by, among other things, making more durable cement (see Colombo, column 3 lines 49-67 included below). However, careful review shows that the Colombo passage has nothing to do with the claim limitations in Applicant's claims 251, 252, or 254. These claims relate to determining the "value of commercialization," which is defined in the specification paragraphs 123-127, under the Heading "Methods of Screening Adverse Events For Commercial Value."

> [0124] All adverse event information is not of equal value. "Commercial value" depends on the potential value of making a generic product or device into a proprietary product or device, or preventing a proprietary product or device from becoming a generic product or device. `Potential commercial value` or `commercial value,` as used herein, means whether it is in the financial interest of an individual or company to seek intellectual property rights on new adverse event information. It can also mean the quantifying of value or projected value based upon obtaining intellectual property rights to the adverse event information.

By contrast, the passage cited by the Examiner from Colombo at column 3, lines 38 to 67 reads:

> Interest in sulfur cement as an alternative to hydraulic cements dates back to the early 20th century. Its corrosion resistant properties made it a candidate for potential use as a construction material in the chemical industry; see Raymont, "Sulphur Concrete and Coatings", New Uses for Sulphur Technology of Canada (SUDIC), Calgary, Alberta, Canada (1978). Product failures were encountered during the use of these early formulations, which have been attributed to internal stresses set up by changes in the crystalline structure upon cooling. Attempts to improve product durability by the addition of modifying agents were either unsuccessful or uneconomical. Since the early 1980's, mandated pollution abatement programs which require sulfur dioxide removal from combustion stack gases have resulted in increased projections of the involuntary supply or sulfur. Sulfur is also a by-product recovered from the refining of natural gas and petroleum. By the year 2000, it is estimated that as much

> as 85-90% of all sulfur production will result from these clean-up operations, possibly yielding over 2.5 X 10^7 tons per year; see Shelton, J. E., "Supply and Demand for Sulphur in the United States", Sulfur '81, Calgary, Alberta, Canada, May 25-28, 1981. (line 60) In an attempt to develop new, commercially viable uses for this by-product material, in 1972 the U.S. Bureau of Mines (USBM) initiated a Sulfur Utilization Program. Modified sulfur cement was developed employing readily available and relatively inexpensive chemical modifiers which significantly improve product durability. Modified sulfur cement is now commercially available under license from the U.S. Department of the Interior.

In addition, the Examiner has rejected claim 258 because the combined references allegedly further teach "drug interaction," (see phrase in bold for emphasis passage below cited by Examiner from Leet at column 18, line 50-65, which Applicant's have extended to column 19, line 12 for discussion).

> After reviewing the protocol, the physician writes an order (at step 18) to treat the patient. (Alternatively the order can be written immediately after the diagnosis is made, without first consulting the DRG protocol 14). The order often takes the form of a direction that a particular medication be given to the patient. That drug order is then communicated to the pharmacy at step 20 (for example via a hospital computer network), and the pharmacist reviews the drug order at step 22. The pharmacist also reviews the DRG protocol at step 24, and may also perform optional reviews at step 26, for example by consulting databases such as 28a (linked to patient records 29) containing patient laboratory data, clinical drug database 28b which contains drug information, drug inventory and cost database 28c, drug administration cost calculation program 28d, **drug interaction database 28e** (which also consults patient records 29 to detect any drug interactions with medications already prescribed to the patient which are listed in the patient record), and dosage calculation program 28f which calculates appropriate doses of medication based on patient information (such as weight and renal function retrieved from patient records 29). Dose calculations are often needed to determine the appropriate dosage of a drug according to patient weight or in view of comorbid conditions (such as renal failure). **If this pharmacist review indicates that the physician order entered at step 18 varies from the DRG protocol recommendations, or if other problems are noted, then at step 28 a message 30 is sent to the physician to call attention to this variance or problem**. If no such problem is noted, then the order is filled at step 32, and the prescribed treatment is given to the patient. (emphasis added by Applicant)

Yet upon careful examination, the combined references fail to even mention *developing novel uses based on novel adverse event*s. Consequently, the reference to "drug interaction" is simply not relevant to, or used in a context that could render Applicant's claim 258 unpatentable. The review in Leet, referred to above and shown in

bold-faced type by Applicant, is made by the pharmacist, who then must report any "variance or problem" to the physician for further action. No new use is developed by the pharmacist based upon his findings, and if the physician acts on the information given to him by the pharmacist – then it is not a new (novel) adverse event identified by the physician. Action by the physician is not responsive to his own discovery, if the pharmacist made the discovery first, thus it does not fall within the elements of Applicant's claimed invention.

Accordingly, the obviousness rejections are improper, and Applicant respectfully asks that they be withdrawn in light of Applicant's comments.

Response to the Rejection under 35 U.S.C. §103(a)

The Examiner has rejected Applicant's claims 253 and 255 under 35 U.S.C. §103(a), as obvious and unpatentable over Leet (US Pat. No. 6,000,828), Rivette (US Pat. No. 5, 991,751) and Colombo (US Pat. No. 5,678,234), and in further view of Risen *et al.* (US Pat. No. 6,018,714). In making this rejection, the Examiner acknowledges that, even when combined, Leet, Rivette and Colombo fail to disclose Applicant's claims 253 and 255 obvious because the cited references do "not disclose [Applicant's] commercializing step." In an effort, therefore, to follow Applicant's disclosure, the Examiner has attempted to add the abstract of the Risen's patent for its "commercialization step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information."

The Risen abstract reads:

> Disclosed herein is a method of providing protection against an unexpected change in value of an intellectual property asset, which includes: (a). obtaining a description of at least one intellectual property asset of a first party, (b). determining a value of the at least one intellectual property asset, (c). determining a cost of providing compensation for an unexpected change in value of the at least one intellectual property asset, and (d). offering to provide compensation for at least a portion of any unexpected change in value of the at least one intellectual property asset to a person with an interest in the first party. A corresponding data processing system, insurance proposal form and computer-generated insurance policy form also are disclosed. The method, system and forms of the invention can be used, for example, as part of a "due diligence" analysis in the context of the purchase and/or sale of intellectual property assets."

Applicant responds that Risen describes a system for providing insurance if the value of an intellectual property decreases. However, Risen's teachings are irrelevant to

Applicant's claims 253 and 255 which relate to "*commercialization*," specifically as the invention relates to obtaining profit from sale of adverse event information. In fact, Risen fails to describe how one would generate additional profit from selling products with additional or novel adverse event information in their marketing sale information. This distinction is particularly true since in the past new adverse event information had always been included in pharmaceutical package inserts without generating additional profit. Commercialization of an adverse event has to do more than simply placing a warning on a label. One has to obtain specific profit for having it on the label and that value must be generated through a sale, as opposed to a use of a product.

The definition of "commercialize" and "commerce" is provided in attached Exhibits D and E. The following definitions come from Webster's dictionary (http://www.m-w.com). Commercialize means a) to manage on a business basis for profit; b) to develop commerce in. Commerce means the exchange or buying and selling of commodities on a large scale involving transportation from place to place. This is not provided by Risen to fill the deficiency in the Examiner's finding that Applicant's invention is obviousness when Leet, Rivette and Colombo are combined.

Accordingly, the obviousness rejection of these claims is improper, and Applicant respectfully asks that it be withdrawn in light of Applicant's comments.

Response to the Rejection under 35 U.S.C. §103(a)claims 259-293

The Examiner has rejected Applicant's claims 259 to 293 as "rejected over the prior art made of record." Presumably the Examiner is relying upon 35 U.S.C. §103(a) as the basis for the unpatentability rejection, although the basis for the rejection is not provided, nor has Applicant been told the particular references the Examiner is relying upon from among the many that have been cited on the record. In fact, it is impossible for Applicant to respond to such a rejection unless the basis for the rejection is provided.

The MPEP at 706.02(j) clearly states that regarding the "Contents of a 35 U.S.C. 103 Rejection" the Examiner must provide the following information:

> 35 U.S.C. 103 authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:
>
> (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,

> (B) the difference or differences in the claim over the applied reference(s),
> (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
> (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

The MPEP at 706.02(j) further states that "The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done," and refers the Examiner to MPEP § 2144 - § 2144.09 for examples of reasoning supporting obviousness rejections. Then the MPEP continues with why it is critical that the Examiner's basis for the rejection be clearly provided, so that – "applicant can be given fair opportunity to reply."

> It is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply. Furthermore, if an initially rejected application issues as a patent, the rationale behind an earlier rejection may be important in interpreting the scope of the patent claims. Since issued patents are presumed valid (35 U.S.C. 282) and constitute a property right (35 U.S.C. 261), the written record must be clear as to the basis for the grant. Since patent examiners cannot normally be compelled to testify in legal proceedings regarding their mental processes (see MPEP § 1701:01), it is important that the written record clearly explain the rationale for decisions made during prosecution of the application.

The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966), focused on the procedural and evidentiary processes in reaching a conclusion under section 103. As adapted to ex parte procedure, Graham is interpreted as continuing to place the "burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103." *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984) (In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art.) The examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Only after the case of obviousness has been established, does the burden of going forward shift to the Applicant.

In this case, since the Examiner has offered no legitimate basis for the rejection of claims 259 to 293 as "rejected over the prior art made of record," applicant has not been

given a fair opportunity to reply. Accordingly, the obviousness rejection of these claims is improper, and Applicant respectfully asks that it be withdrawn.

For a §103 rejection of a patent claim to be valid, the three criteria set forth below must be met: First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

To permit applicant's to rebut assertions of §103 obviousness, the courts have established recognized secondary considerations for responding to an obviousness rejection: (1) evidence of unexpected or nonobvious properties or advantages as compared with the closest prior art; and (2) evidence of real world activities, such as commercial success of the invention or providing a solution to a long-felt need in the art. Condition (1) may be met by either evidence of advantages or unexpected results produced by the invention, or by affidavit or declaration under 37 C.F.R. 1.132. Accordingly, Applicant provides evidence in the attached sworn Declaration of Dr. John B. Classen under 35 U.S.C. §1.132, which demonstrates the ultimate evidence of nonobvious, by offering real world evidence of copying and infringement of Applicant's claimed invention by another, and evidence of that third party's commercial success using Applicant's invention despite expressed skepticism by experts. When combined, these demonstrated secondary considerations clearly demonstrate that, contrary to the Examiner's conclusions, Applicant's invention was not, and is not, obvious over the cited prior art.

It is respectfully submitted, therefore, that Applicant's pending claims are in condition for allowance, and Applicant respectfully requests that allowance be granted at the earliest date possible. Should the Examiner have any questions or comment regarding Applicant's amendments or response, the Examiner is asked to contact Applicants undersigned representative at (215) 772-7550.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-2424. A duplicate copy of this Amendment and Response is enclosed.

Respectfully submitted,

Date: March 29, 2007

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